

REMARKS

In the office action dated May 20, 2004, the Examiner stated that the PTO has not received a certified copy of Danish priority document PA 1998 01433. A certified copy of the document will be sent in due course.

Applicant has amended claims 163-174 and added new claims 175-178 to clarify and further define the invention. Defendant claims 175-177 recite narrower ranges for the interior average depth of the sample compartment which were originally in claim 163. New dependent claim 178 has also been added to include a propelling means. Support for this claim can be found on page 12, lines 5-7 of the specification. No new matter has been added by addition of these claim amendments.

The Examiner objected to the drawings under 37 C.F.R. §1.84(p)(5) because reference signs in Figs 1-3, and 6 were either mislabelled or missing. Applicant has amended the drawings and submitted replacement sheets for Figs 1-3, and 6.

The Examiner objected to the Abstract because it contained the legal term "means" and for using the phrase "the present invention relates to" as this can be implied and is unnecessary. The Applicant has submitted a replacement Abstract in response and requests that this objection be withdrawn.

The Examiner objected to claims 163, 164, 166, 169 and 170 because of various language informalities. Applicant has amended these claims in response and requests that these objections be withdrawn.

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Rejections under 35 U.S.C §112, second paragraph

10 The Examiner has rejected claims 166-167, 170-171 and 173 as being indefinite for failing to particularly point out and distinctly claim the subject matter, which Applicant regards as the invention. As stated above, Applicant has amended the recited claims as follows:

15 The phrase "the part of the flow channel" in claims 166 and 167 has been rephrased to "part of the channel";

20 Claim 166 has been divided in two, i.e. "and/or comprises one or more mixing chambers" has been deleted from claim 166. A new claim 174 has been introduced:

25 *A device according to claim 163, wherein the flow system comprises one or more mixing chambers.*

30 The grouping in claim 168 has been rephrased to: "...means selected from the group consisting of: stop valves, one way valves, pressure valves and speed reduction valves."

The grouping in claim 170 has been rephrased to:  
"....the spectrophotometric measurement being selected from  
the group consisting of: mid-infrared attenuation, near-  
infrared attenuation, visible attenuation, ultra-violet  
attenuation, photoluminescence, Raman scatter, and  
nuclear magnetic resonance."  
5

The term "direction" has been replaced by  
"plane" in claim 172.

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The Applicant has deleted the term "substantial"  
from claims 166, 167 and 172.

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The Applicant has deleted the term "e.g." from  
claim 170.

The Applicant has replaced the term "thickness"  
in claim 171 with "depth".

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The Applicant has amended claims 171 and 173, to  
recite the broadest ranges, and has added new claims 175-  
177 to recite narrower ranges.

**Claim rejections under 35 USC §102(e)**

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The Examiner rejected claims 163-165, 167-169,  
171 and 173 under 35 U.S.C. §102(e) as being anticipated  
by Wilding et al., (US 5,726,026). Applicant  
respectfully traverses this rejection. Applicant is  
confused by the language of the rejection where the  
30 Examiner discusses that it is "obvious to one of skill in

the art...that the device can be disengaged from a detection device" in the context of a §102 rejection.

In the amended claim set filed herewith, claim 5 163 has been amended to introduce the feature of "the device having no sample outlet". Basis for this feature can be found on page 7, lines 11-13 of the specification:

10 "For some embodiments, the devices are constructed without a sample outlet, whereby the sample remains in the device after the assessment has taken place."

15 Wilding et al. (US 5,726,026) do not teach devices without a sample outlet. In Wilding, the sample preparation devices as well as the detection devices and polynucleotide amplification devices associated therewith, all comprise a sample outlet. Furthermore, Yager et al. (US 5,716,852) and Kricka et al (US 20 5,744,366) do not teach devices without a sample outlet either. Moreover, Masuda et al. (US 4,472,498), Ozaki et al. (US 5,754,289), Fesik et al. (US 5,804,390) and Allen et al. (US 5,190,857) also do not teach devices without a sample outlet as well.

25 "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Thus, none of the prior art documents cited by the Examiner teach a device without sample outlet. Because the references do not recite each and every

element of the amended claims 163-178 they cannot be anticipated under §102(e) and the Applicant respectfully requests the rejection be withdrawn.

5           The Examiner further argues that while Wilding et al. do not teach that the sample device can be disengaged from the detection device and disposed, it teaches that unreacted reagent, reaction products and sample are confined in the device for subsequent 10 disposal. Therefore if it is disposable, it is inherently mobile. Applicant disagrees that Wilding "inherently anticipates" the disengaging limitation claimed in the present invention.

15           The embodiment described by the Examiner in the Wilding reference has an outlet. As stated above, the device of the present invention does not have an outlet. Additionally, the embodiment at col. 15, lines 54-61, describes a unit used for biological assays that measure 20 binding. A binding substrate is present in the device in order to bind with an analyte in the sample. Obviously, if one is to measure if an analyte binds to a particular substrate, the reaction mixtures have to remain bound to the substrate. The present invention, however, does not 25 measure binding and does not contain binding substrates. Therefore this embodiment does not anticipate the present invention and the Applicant respectfully requests the rejection be withdrawn.

**Rejections under 35 U.S.C. §103(a)**

The Examiner has rejected claim 166 as obvious over Wilding et al. in view of Yager et al. (US 5,716,852). The rejection is respectfully traversed.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. Moreover, the teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure.

In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

The burden is on the examiner to establish a *prima facie* case of obviousness of the claimed subject matter over prior art references. In re Deuel, 51 F.3d 1552, 1557, 34 USPQ2d 1210, 1214 (Fed. Cir. 1995). Only

after that burden is met must the applicant come forward with arguments or evidence in rebuttal. Id. To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the 5 prior art. In re Royka, 490 F.2d 981, 180 USPQ 580 (CCPA 1974).

Applicant respectfully submits that Yager et al. (US 5,716,852) and Kricka et al. (US 5,744,366) do not 10 teach devices without a sample outlet. Moreover, Masuda et al. (US 4,472,498), Ozaki et al. (US 5,754,289), Fesik et al. (US 5,804,390) and Allen et al. (US 5,190,857) also do not teach devices without sample outlet.

Applicant submits that the Examiner has failed 15 to establish a *prima facie* case of obviousness with regard to claim 166 because the combination of Wilding et al. in view of Yager et al. does not teach each and every element of the claimed invention.

20 In Wilding et al., the flow channel of the device is connected to the flow channel of the appliance. Thus, clearly, the outlet is an essential feature of the Wilding device. Yager et al. teaches the analysis of

sample streams, which also clearly requires an outlet. Thus, combination of these two references does not contain all the limitations of claim 166 and therefore it also cannot provide the basis for a *prima facie* obviousness rejection.

Furthermore, Applicant submits that the Examiner has not provided evidence that one of skill would have been motivated to combine Wilding with Yager to arrive at the claimed invention. Applicant asserts that there would have been no motivation for one of skill in the art to modify the devices taught in Wilding and Yager so as to remove the sample outlet, because the devices in the both references are used in fundamentally different methods. Both Wilding et al. and Yager et al. are intended to measure a sample coming from flowing streams of analyte. As such, one of skill in the art would not look to Wilding or Yager to design an analytical device where the device stops the analyte stream. Therefore without evidence of motivation to combine these references, there cannot be a basis for a *prima facie* obviousness rejection. Applicant respectfully requests that the rejection be withdrawn.

The Examiner has rejected claim 170 of the present invention under 35 U.S.C. §103(a) as obvious over Wilding et al., in view of Masuda et al. (US 4,472,498), Ozaki et al. (US 5,754,289), Fesik et al. (US 5,804,390) 5 and Allen et al. (US 5,190,857). Applicant respectfully traverses this rejection.

For the same reasons stated with regard to claim 166, Applicant submits that Masuda et al., Ozaki et al., 10 Fesik et al. and Allen et al. do not teach devices without sample outlet. As such, Applicant submits that the Examiner has failed to establish a *prima facie* case of obviousness with regard to claim 170 because the combination of Wilding et al. in view of Masuda et al., 15 Ozaki et al., Fesik et al. and Allen et al. do not teach each and every element of the claimed invention. Applicant therefore, respectfully requests that the rejection be withdrawn.

20 The Examiner has rejected claim 172 of the present invention under 35 U.S.C. §103(a) as obvious over Wilding et al., in view of Kricka et al. (US 5,744,366). The Examiner states that at the time of the invention, it would have been obvious to one of skill in the art to

include in the device of Wilding, a device with chambers having widths and lengths on the order of 1 mm or larger, wherein the chamber is fabricated in a substrate and a cover is disposed over the substrate as taught by Kricka,  
5 in order to allow adequate cell movement within the chamber. Applicant respectfully traverses this rejection.

Applicant submits that Kricka et al. do not  
10 teach devices without sample outlet. Kricka et al. teaches e.g. in column 11, lines 17-21 "...and target chamber 22 open to the atmosphere via ports 16a and 16b. In an alternative embodiment, the target chamber may be omitted, but should be replaced with a port, disposed  
15 anywhere over the flow system, to facilitate filling or evacuating the device" (emphasis added)

Thus, Kricka et al. (as well as all the other cited references) clearly teaches the requirement for an  
20 outlet. Removal of the outlet from any of the devices disclosed in these three documents would render them unsuitable for the uses disclosed in the documents. A clear advantage of the lack of outlet of the present invention is that there is less risk that the sample will

leak from the device and thus contaminate the surrounding environment. Furthermore, the lack of an outlet in the present invention provides greater ease for keeping the sample at standstill during exposure, which is preferable  
5 when performing counting of cells in a liquid.

As such, Applicant submits that the Examiner has failed to establish a *prima facie* case of obviousness with regard to claim 172 because the combination of  
10 Wilding et al. in view of Kricka et al. does not teach each and every element of the claimed invention. Applicant therefore, respectfully requests that the rejection be withdrawn.

15 In conclusion, Applicant asserts that none of the references cited by the Examiner teaches a device without outlet. Thus, no combination of prior art documents leads to a device with all the limitations of the amended claims. Moreover, in view of the general teachings of the  
20 cited prior art documents, the skilled person would not be motivated to remove the outlet, as this would make them unsuitable for the uses described in the prior art. Nothing in the prior art teaches or suggests the technical solution provided by the inventor.

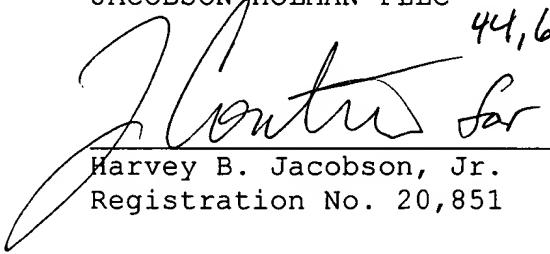
All of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot.

Applicant therefore respectfully requests that the  
5 Examiner reconsider all currently outstanding rejections,  
and that they be withdrawn. It is believed that a full  
and complete response has been made to the outstanding  
Office Action and, as such, the present application is in  
condition for allowance. If the Examiner believes, for  
10 any reason, that personal communication will expedite  
prosecution of this application, the Examiner is invited  
to telephone the undersigned at the number provided.

15 Respectfully submitted,

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Date: September 17, 2004  
Atty. Docket: 12596/P666116US0  
HBJ/JGC

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AMENDMENTS TO THE DRAWINGS

In Figure 1:

Replace reference sign "609" with "109".

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In Figure 2:

Replace reference sign 202 with 204;

Replace reference sign 203 with 205;

Replace reference sign 204 with 206;

10 Replace reference sign 205 with 207;

Replace reference sign 206 with 211; and

Replace reference sign 207 with 212.

In Figure 3:

15 Replace reference sign 801 with 301;

Replace reference sign 802 with 302; and

Replace reference sign 803 with 303.

In Figure 6:

20 Add reference sign 204, 213, 214, 215, and 216 where indicated in the replacement drawing.



WO 00/28297

PCT/DK99/00605

1/6

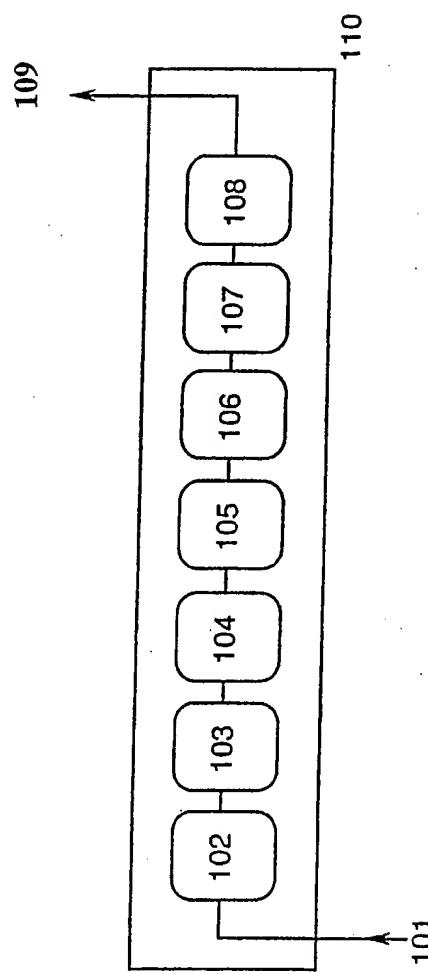
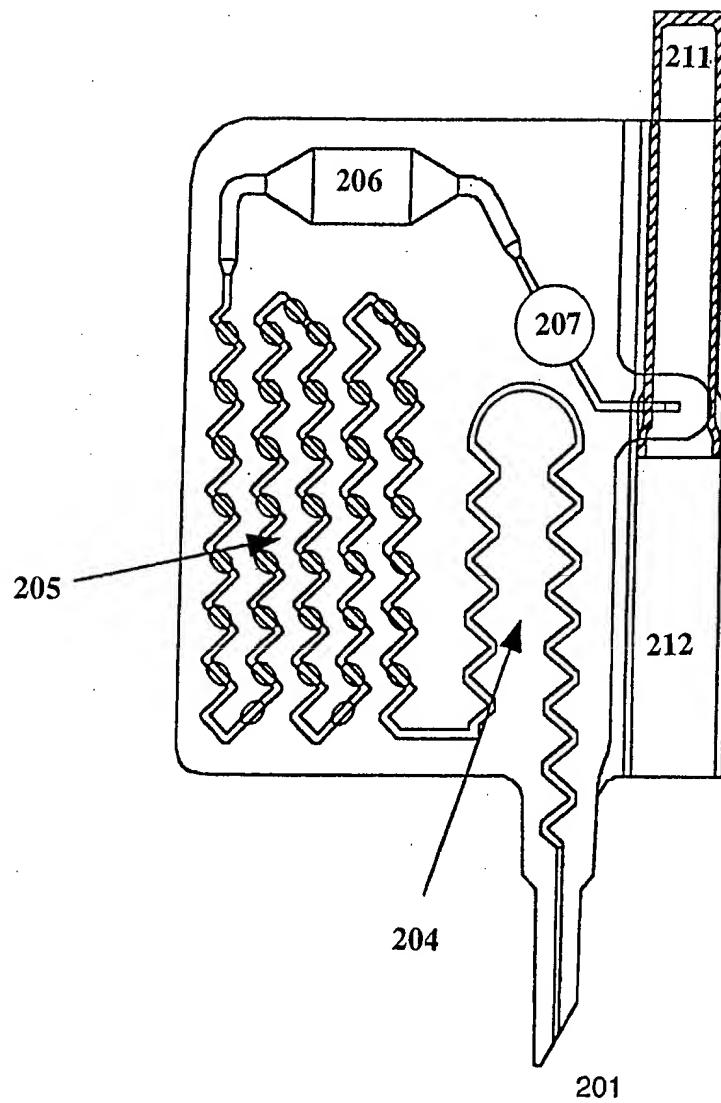


Figure 1

2/6



**Figure 2**



WO 00/28297

PCT/DK99/00605

3/6

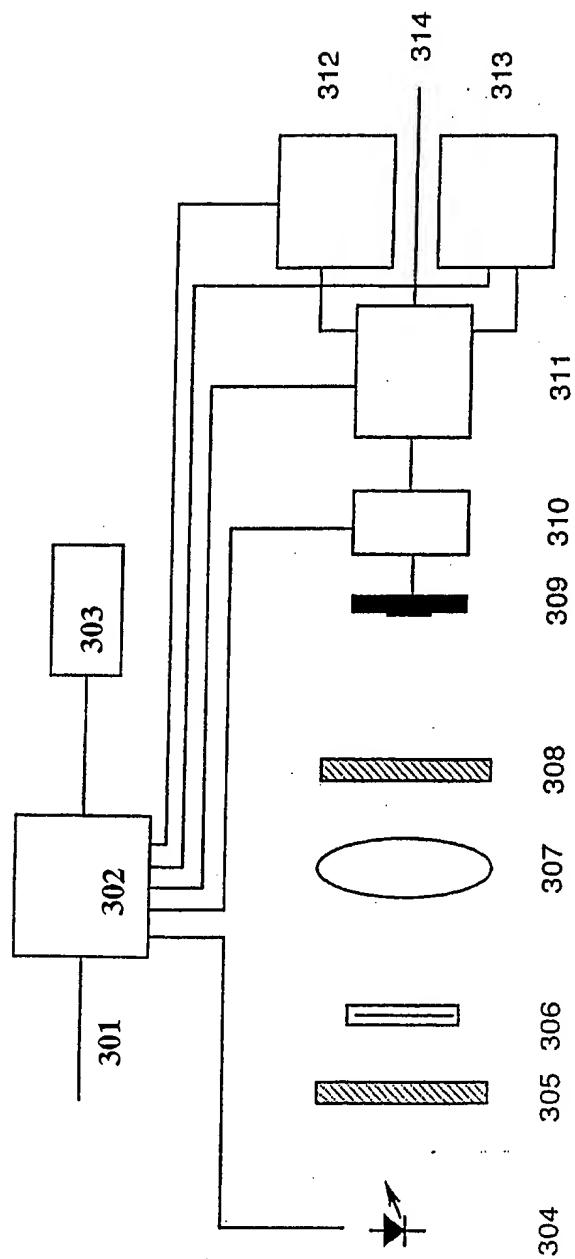


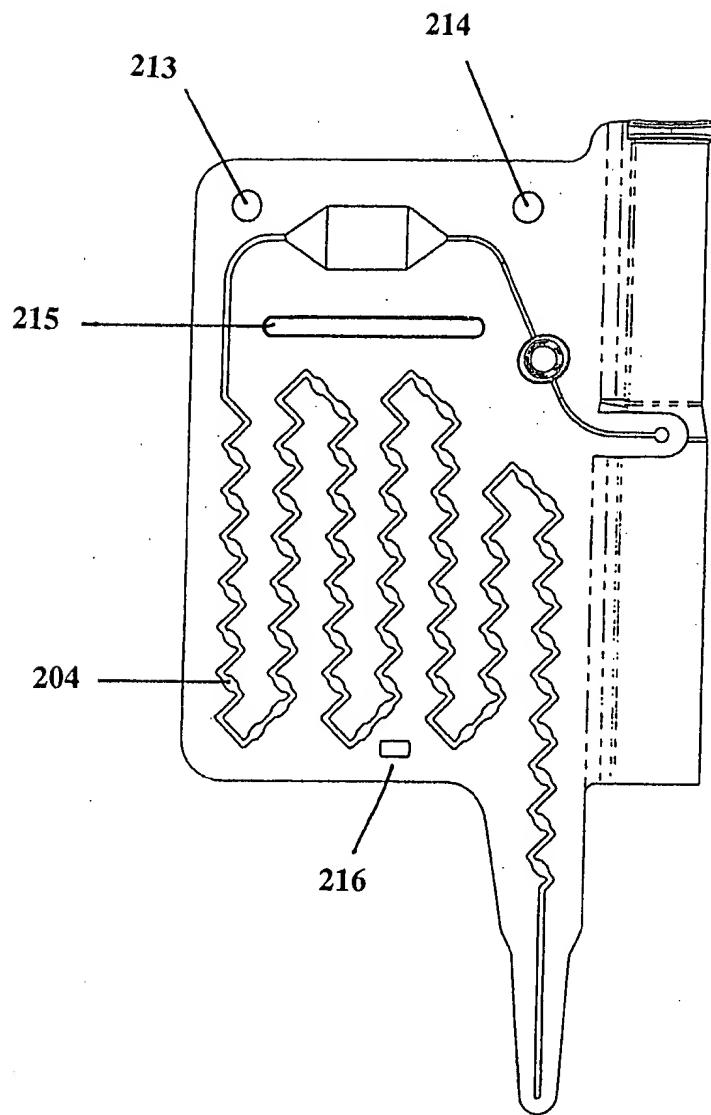
Figure 3



WO 00/28297

PCT/DK99/00605

6/6



**Figure 6**